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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/827,106	04/19/2004	Gopi M. Venkatesh	451194-107	1448

27805 7590 11/13/2006

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EXAMINER	
SAMALA, JAGADISHWAR RAO	

ART UNIT	PAPER NUMBER
1618	

DATE MAILED: 11/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/827,106	VENKATESH ET AL.	
	Examiner	Art Unit	
	Jagadishwar R. Samala	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-24 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-24 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 11/19/04; 12/19/05, 05/08/06
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Application Status

1. Applicant's response to the Office Action was acknowledged April 19, 2004

Claim Disposition

2. Claims 1-24 is/ are pending and are under examination.

Information Disclosure Statement

4. The Information Disclosure Statement filed on November 19, 2004; December 19, 2005 and May 08, 2006 has been received and entered the references cited on the PTO-1449 Form have been considered by the examiner and a copy is attached to the instant Office Action.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Ohta, Motohiro et al., (EP 0 914818 A1 here after '818).

Claims 1-24 are drawn to a tablet composition and method of manufacturing tablet that disintegrates in the oral cavity comprising a compressed blend of a rapidly

dispersing microgranules prepared by granulating a sugar alcohol or saccharide having an average particle size less than 30 microns, a disintegrant and a taste masked microcapsule containing at least one drug.

The patent '818 discloses a production method of a tablet characterized by compressing powdered mixture comprising sugar alcohol or saccharide each having an average particle diameter of not more than 30 microns ground by means of a hammer mill or a jet mill or the like, an active ingredient, and a disintegrant under the presence of an easily volatile disintegrating adjuvant and thereafter the disinitegrant adjuvant is volatilized. (see 0004) The disintegrant mainly used such as crospovindone, crosscarmellose sodium, low substituted hydroxypropylcellulose or the like which is widely used for drugs and food (see 0016). Also sugar alcohol used were D-mannitol, sorbitol, and saccharide used were lactose and glucose or like which is widely used for drugs and foods. The amount of sugar alcohol or saccharide is preferably about 60-95 % by weight of tablet (see 006 and 0019).The amount of taste masked active ingredient is 0.01–30 % , and the amount of disintegrant present is preferably about 1-30mg per dosage, and more preferably 1-10 % per one tablet (see 0021). The patent '818 also discloses the use of binders such as hydroxypropylcellulose, polyvinylpyrrolidone, hydroxymethlylcellulose, partially saponificated polyvinyl alcohol methylcellulose, pullulan or the like, sour agent as citric acid, malic acid, adipic acid ascorbic acid or like, sweetening agent is Aspartame ™, saccharin, glycyrrhizic acid or the like, flavoring agent is lemon, orange, pine, mint, menthol or the like, colorant is yellow iron sesquioxide, red iron sesquioxide, tar color or the like optionally as additional

pharmaceutical ingredients (see 0023). The patent further discloses the following drugs such as hyprotic, anxiolytic, antiepileptic, psychoneurosis agents, drug for central nervous system, peripheral nervous system, autonomic nervous system, skeletal muscle relaxant, antiarrhythmic agent, angiotonic, vasodilator, hyperlipemia, antidiarrheal drug, drug for peptic ulcer such as azulene, L-glutamine, aceglutamide aluminium, cetraxate hydrochloride, cimetidine and so on (see 0007 –0015). The teaching of the patent '818 possesses all the steps required as recited in claims. Thus, all the claims are anticipated.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 1-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Percel et al. (US 6,451345 here after '345) in view of Masaki et al. (US 5,466,464 here after '464).

Percel discloses a taste masked antibiotic tablet comprising a primary ethylcellulose coating of Linezolid needle-like crystals with a median particle size of 20 microns by solvent coacervation, an optionally blended with other pharmaceutically acceptable excipients such as binders like hydroxypropylcellulose, microcrystalline cellulose, disintegrants include cornstarch, lactose, mannitol, sucrose, crospovidone,

flavors, sweeteners, suspending agents and/or preservatives and filled into unit dose containers or compressed into fast-disintegrating/effervescent/chewable tablets.(see abstract, column 1, lines 17-24 and column 5, example 7).

Percel fails to disclose H_2 antagonists such as ranitidine, cimetidine , and famotidine and so on as a pharmaceutically active ingredient included therein. However, the use of H_2 –receptor antagonist useful for inhibiting gastric secretion and treating ulcers is well known in the art as shown by Masaki.

Masaki discloses a process for the production of an intrabuccally disintegrating solid tablet preparation comprising an active ingredient (i.e. H_2-receptor antagonists such as famotidine, cimetidine, ranitidine, and a sugar comprising lactose and/or mannitol (see column 3, lines 7-20).

It would have been obvious to one of ordinary skill in the art to modify the Parcel chewing tablets to include an active medicament, H_2-receptors as an additional pharmaceutical active medicamnet because Masaki teaches that addition of H_2-receptor antagonists as a active medicament greatly reduces gastric acid secretion systemically and healing ulcers. One of ordinary skill in the art would have been motivated to include the H_2-receptor antagonists as an additional pharmaceutical active medicament disclosed by Parcel because H_2-receptors antagonists taught by Masaki, while having similar physiological functions, provides an additional treatment for upper abdominal pain/discomfort and heartburn, indigestion, sour stomach, and other gastrointestinal disorders including gastro-oesophageal reflux.

Conclusion

1. No claims are allowed at this time.

2. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jagadishwar R. Samala whose telephone number is (571)272-9927. The examiner can normally be reached on 8.30 A.M to 5.00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571)272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

VICKIE KIM
PRIMARY EXAMINER

Jagadishwar R Samala
Examiner
Art Unit 1618